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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,559	06/30/2003	Andrew D. Murdin	032931-0264	7270

22428 7590 03/30/2004

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EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,559	MURDIN ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-11,26-28,35 and 39-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *8-11,26-28,35 and 39-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/14/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed 1/14/04 was entered. Claims 8-11, 26-28, 35 and 39-45 are currently under examination.

Specification

1. This application filed under former 37 CFR 1.62 lacks the necessary reference to the prior application. A statement reading "This is a Continuation of Application No. 5/3/200, filed 5/3/200, now abandoned." should be entered following the title of the invention or as the first sentence of the specification.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 26, 27, 28, and 43-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 'a method for preventing or treating *Chlamydia pneumoniae* infection', does not reasonably provide enablement for 'a method for preventing or treating [any] *Chlamydia* infection". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant methods claims are drawn to treating or preventing infection with *Chlamydia* of any species. However, the instant specification only provides results which teach that the claimed vaccine vectors can treat or prevent infection with *C.pneumoniae*. The vaccine vector uses a nucleic acid which encodes a protein

specific to *C.pneumoniae*. The prior art and instant specification at page 2, lines 1-5, teach that *C.pneumoniae* is antigenically, genetically and morphologically distinct from other Chlamydia species, such as *C.trachomatis, C.pecorum* and *C.psittaci.* The bacterial vaccine art is highly unpredictable. It is unlikely that an antigen specific to *C.pneumoniae* will have the ability to confer protection against other antigenically, genetically and morphologically distinct *Chlamydia* species. The specification fails to teach that the claimed vaccines are capable of cross-protection. Accordingly, the scope of the claims is not enabled. Applicants should submit additional evidences that demonstrate the vaccine's ability to cross-protect or limit the current claims to methods which treat or prevent *Chlamydia pneumoniae* infection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 8-11, 35 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalman et al (Nat. Genet. April 1999. 62(3): 880-886) in view of Griffais (US 6,559,294 B1).

Kalman et al teach the complete genome of *C.pneumoniae.* Kalman et al teach the nucleotide coding sequence and the deduced amino acid sequence of a 76kDa *C.pneumoniae* protein. This protein is 100% identical to Applicant's SEQ ID NOs: 2 and 6, as well as a nucleic acid which is a 100% match to SEQ ID NO: 1. Although Kalman

et al do not specifically teach an expression vector comprising the isolated nucleotide sequence encoding SEQ ID NO:2, 4 or 6 linked to a promoter for expression of the polypeptide, it would have been prima facie obvious to one of ordinary skill in the art to operatively link said nucleotide sequence to a promoter for expression of the polypeptide in a host cell (mammalian or bacterial) in order to produce a polypeptide and to make antibodies for detection of the *C.pneumoniae* pathogen. Griffais et al teach the recombinant production of polypeptides identified through analysis of the *C.pneumoniae* genome and teach that these polypeptides may be used in detection methods or to generate antibodies. Promoters and other elements necessary to allow the expression and/or the secretion of the nucleotides sequences in a given host cell are specifically taught. See Column 46, lines 14-25. Griffais specifically teaches the use of mammalian host cells (see column 46, lines 14-25), as well as the use of CMV as a promoter (column 46, line 45), and they both would have been obvious choices to those of ordinary skill in the art at the time the invention was made when making the recombinant proteins. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to recombinantly produce the antigen identified by Kalman et al specifically because said protein would be useful in detection of *C.pneumoniae* and because the prior art, as demonstrated by Griffais, teach that doing so was routine in the art.

The terms "pharmaceutical composition" and "vaccine" are intended uses only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A "physiologically acceptable carrier" reads on water and therefore would be inherent in the preparation of the vectors. Although the teachings of Kalman and Griffais et al do not specifically recite the expression plasmids pCACPNM555a, pCAI555 or pCAD76kDa, the structure of these plasmids is taught by the combined teachings of Kalman and Griffais et al and therefore would be identical to that of pCACPNM555a, pCAI555 or pCAD76kDa, absent evidence to the contrary.

Prior Art Made of Record:

6. Griffais (US 6,559,294 B1). Griffais et al teach the genome of *Chlamydia pneumoniae*, as well as open reading frames for some specified proteins. There are local matches across the *C.pneumoniae* genome which are 99% identical to Applicants' SEQ ID Nos: 1, 3 and 5. However, the genome taught by Griffais is **1,230,025 nucleotides in length** and Griffais fails to identify any ORFs which would encode the full-length sequences of SEQ ID Nos:2, 4, or 6. SEQ ID NO: 776 of Griffais is 68% identical to SEQ ID NO:2. Those of ordinary skill in the art would not be able to determine which portion of the 1,230,025 length genome taught by Griffais et al would encode the proteins described in the instant application since they were not identified in the reference. Accordingly, Griffais does not teach or suggest the claimed invention which is drawn to a vaccine vector comprising an isolated nucleotide sequence which encodes a polypeptide of SEQ ID Nos: 2, 4 or 6, wherein the nucleic acid molecule is operatively linked to a promoter for expression of the polypeptide in a mammalian cell.

Status of Claims:

7. Claims 26, 27, 28, and 43-45 are free of the prior art. Claims 26, 27, 28, and 43-45 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

8. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 872-9306 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

J Graser 3/29/04

Jennifer Graser
Primary Examiner
Art Unit 1645